

### REMARKS

This Amendment is submitted in response to an Office Action dated November 14, 2002. Applicant notes with appreciation that in the Office Action, the Patent Office acknowledged Applicant's election with traverse of Claims 1-14, found the amendments to the claims to be persuasive, and stated that all of Claims 1-20 would be examined. Because the Patent Office also rejected and examined Claims 21-26, Applicant assumes the Patent Office intended to state that all of Claims 1-26 would be examined.

The Patent Office rejected Claims 1-14 and 21-26 under pre-AIPA 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,059,802 to *Ginn*. Further, the Patent Office rejected Claims 15-20 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,759,150 to *Konou et al.* Applicant notes that Claims 25-26 depend from Claim 15 and thereby assumes the Patent Office is rejecting Claims 25-26 under 35 U.S.C. §102(b) as being anticipated by *Konou et al.* and not under pre-AIPA 35 U.S.C. §102(e) as being anticipated by *Ginn*.

By the present Amendment, Applicant submits that the application is in condition for allowance for the reasons that follow.

With respect to the rejection of Claims 1-14 and 21-26 under pre-AIPA 35 U.S.C. §102(e) as being anticipated by *Ginn*, Applicant submits the Claims are allowable over *Ginn* for the reasons that follow.

The Patent Office alleges that *Ginn* teaches a catheter introducer device having:

a cylindrical body defining a cross with a length defined between a pointed end and a flat end. A first part and a second part, wherein the first and the second part defines the cylindrical body. Locking mechanism (figs 6-7) where the first part and the removable second part are locked together. The pointed end of the cylindrical body gradually tapers to the cylindrical portions. A recess

portion along the length of the first portion and a protruding element defined in shape by a right angle located along the recessed portion of the first part. The recess portion may readily accept the protrusion along the length of the removable second part. A first hole located a distance from the pointed end of the cylinder. A leg attached to the bottom end of the cylinder. A second hole located on the leg of the cylinder and a thread connected (locking mechanism) to the cylinder from the second hole to the first hole. A groove or plurality of holes cut into the cylinder.

Claim 1 of the present invention defines a catheter for placing within a body. The catheter has a flexible hollow body defining a length between a top end and a bottom end wherein the top end is closed and wherein the top end tapers to a cylindrical tube. The catheter defined by Claim 1 further has a cylindrical body defining a cross, a first part having a uniform width, and a second part defining a cross wherein the first part and the second part define the cylindrical body and further wherein the top end of the flexible hollow body is removably attached to the second part of the cylindrical body.

Further, Claim 7 of the present invention defines a catheter for placing within a body. The catheter requires a flexible hollow body defining a length between a top end and a bottom end wherein the top end is closed and tapers to a cylindrical tube. The catheter defined by Claim 7 further has a cylinder having a length defined between a pointed end and a second end wherein the top end of the flexible hollow body is removably attached to the pointed end of the cylinder, a first hole located a distance from the pointed end of the cylinder.

Ginn merely teaches a slat assembly for harvesting vascular conduits or vessels. The slat assembly taught by Ginn requires two arcuate slats which are laterally translatable relative to each other. The two slats have similar cross-sections across their width dimensions. To enable the lateral translation of the

assembly, a series of slots are formed in one of the slats, and a corresponding series of pins are secured to the other slat with each pin being slidably contained by a corresponding slot.

Contrary to the assertion made by the Patent Office, Ginn does not teach a first part having a uniform width and a second part defining a cross wherein the first part and the second part define a cylindrical body as required by Claim 1 of the present invention. Nor does Ginn teach a flexible hollow body defining a length between a top end and a bottom end wherein the top end tapers to a cylindrical tube as required by Claim 7 of the present invention. Rather, Ginn teaches an assembly having an arcuate cross-section, not a cylindrical body.

Under 35 U.S.C. §102, anticipation requires that a single reference discloses each and every element of Applicant's claimed invention. *Azko N.V. v. U.S. International Trade Commission*, 808 F.2d 1471, 1479, 1 USPQ 2d 1241, 1245 (Fed. Cir. 1986).

Moreover, anticipation is not shown even if the differences between the claims and the reference are "insubstantial" and one skilled in the art could supply the missing elements. *Structure Rubber Products Co. v. Park Rubber Co.*, 749 F.2d. 707, 716, 223 USPQ 1264, 1270 (Fed. Cir. 1984). Again, Ginn fails to teach or suggest a first part and a second part defining a cross wherein the first part and the second part define a cylindrical body. Further, Ginn fails to teach or suggest or a flexible hollow body having a top end wherein the top end tapers to a cylindrical tube.

Since Ginn fails to disclose the elements defined in independent Claims 1 and 7, Applicant submits that the rejection of independent Claims 1 and 7 under 35 U.S.C. §102(e) is improper and should be withdrawn. Notice to that effect is requested.

Further, with respect to the rejection of Claims 15-20 under 35 U.S.C. §102(b) as being anticipated by Konou et al., Applicant

submits Claim 15 is allowable over Konou et al. for the reasons that follow.

The Patent Office alleges Konou et al. teach an introducer catheter device having:

a first part and a second part wherein the first part and the second part define a cylindrical body and the second part is removable. Locking mechanism located at the flat end of the cylinder. Piercing the skin and the subcutaneous layer of the body with the pointed end of the cylinder body, pushing the cylindrical body through the subcutaneous layer wherein the cylindrical body is exposed outside an exit site of the body; removing the second part of the cylindrical body attaching a catheter to the first part of the cylindrical body pulling the catheter through the subcutaneous layer (fig 53) and once the operation is complete the first part of the cylindrical body is removed from the body. There are suture sites for the instrument to be secured to the body.

Claim 15 of the present invention defines a method for introducing a catheter into a body of a patient wherein the body includes skin and a subcutaneous layer. The method requires the steps of: providing a flexible hollow body defining a length between a top end and a bottom end and having a notch located a distance from the top end; providing a second notch located a distance from the bottom end; providing a first part having a length defined between a pointed end and a flat end; providing a second part having a length defined between the pointed end and the flat end wherein the first part and the second part define a cylindrical body and further wherein the second part is removable; and providing a locking mechanism located at the flat end of the cylindrical body wherein the first part and the second part are locked together.

Konou et al. merely teach a system for evulsing subcutaneous tissue including an endoscope, a dissecting unit, a cavity maintaining unit, ~~a treatment space, and at least one treatment tool.~~ Konou et al. do not teach or suggest a flexible hollow body

having a top end and a bottom end and having a notch located a distance from the top end and a second notch located a distance from the bottom end as required by Claim 15 of the present invention. On the contrary, Konou et al. teach a tunnel shaped cavity maintaining unit and *hard* endoscope. Moreover, Konou et al. do not teach a first part and a second part wherein the first part and the second part define a cylindrical body and further wherein a locking mechanism locks the first part and the second together and further wherein the second part is removable as required by Claim 15 of the present invention. Rather, the excising member taught by Konou et al. has a body formed into an elongated tube, a large diameter pipe formed in the body, and a transparent leading end connected to the leading end of the body.

Under 35 U.S.C. §102, anticipation requires that a single reference discloses each and every step of Applicants' claimed invention. *Azko N.V. v. U.S. International Trade Commission*, 808 F.2d 1471, 1479, 1 USPQ 2d 1241, 1245 (Fed. Cir. 1986).

Moreover, anticipation is not shown even if the differences between the claims and the reference are "insubstantial" and one skilled in the art could supply the missing steps. *Structure Rubber Products Co. v. Park Rubber Co.*, 749 F.2d. 707, 716, 223 USPQ 1264, 1270 (Fed. Cir. 1984).

Again, Konou et al. fail to teach or suggest providing a flexible hollow body having a notch located a distance from the top end and a second notch located a distance from the bottom end of the flexible hollow body. Further, Konou et al. fail to teach or suggest providing a first part and a second part that define a cylindrical body wherein a locking mechanism locks the first part and the second part together and further wherein the second part is removable.

Since Konou et al. fail to disclose the steps defined in independent Claim 15, Applicant submits that the rejection of

independent Claim 15 under 35 U.S.C. §102(b) is improper and should be withdrawn. Notice to that effect is requested.

Further, Claims 2-6, 21 and 22 depend from Claim 1; Claim 8-14, 23 and 24 depend from Claim 7; and Claims 16-20, 25 and 26 depend from Claim 15. These claims are also believed allowable over the references of record for the same reasons set forth with respect to their parent claims since each sets forth additional structural elements and novel steps of Applicant's catheter with introducer and method for using the same. Notice to that effect is requested.

In view of the foregoing remarks and amendments, Applicant respectfully submits that all of the claims in the application are in allowable form and respectfully solicits allowance of the same. If, however, any outstanding issues remain, Applicant urges the Patent Office to telephone Applicant's attorney so that the same may be resolved and the application expedited to issue. Applicant requests the Patent Office to indicate all claims as allowable and to pass the application to issue.

Respectfully submitted,




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**CERTIFICATE OF MAILING**

I hereby certify that this **Amendment** is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Asst. Commissioner for Patents, Washington, D.C. 20231 on February 12, 2003.

  
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VERSION WITH MARKS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend Claim 1 as follows:

1. A catheter for placing within a body, the catheter comprising:
  - a flexible hollow body defining a length between a top end and a bottom end wherein the top end is closed and wherein the top end tapers to a cylindrical tube;
  - a diameter defined by the cylindrical tube;
  - a width defined by the bottom end of the flexible body wherein the width is greater than the diameter;
  - a locking mechanism located on the bottom end of the flexible body;
  - a first notch located a distance from a point at which the top end meets the cylindrical tube; [and]
  - a second notch located a distance from the bottom end;
  - a cylindrical body defining a cross with a length defined between a pointed end and a flat end;
  - a first part having a uniform width and a length defined between the pointed end and the flat end; and
  - a second part defining a cross with a length defined between a pointed end and a flat end wherein the first part and the second part define the cylindrical body and further wherein the top end of the flexible hollow body is removably attached to the second part of the cylindrical body.